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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,299	01/30/2002	Thomas Newmark	9510.101F	7346

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EXAMINER

JIANG, SHAOJIA A

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 06/18/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/058,299

Applicant(s)

NEWMARK ET AL.

Examiner

Shaojia A. Jiang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 13-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) g.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on April 8, 2003 in Paper No. 7 wherein claims 1-12 have been amended. Currently, claims 1-24 are pending in this application.

As indicated in the previous Office Action, Claims 13-24 drawn to a method herein are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant's remarks, filed April 8, 2003 in Paper No. 7 with respect to the rejection made under 35 U.S.C. 112 first paragraph for lack of scope of enablement in claims 1-12, "a supercritical extract" of record stated in the Office Action dated January 8, 2003 has been fully considered and is found persuasive to remove the rejection. Therefore, the said rejection is withdrawn.

Applicant's amendment which amends claim 5, filed April 8, 2003 in Paper No. 7 with respect to the rejection made under 35 U.S.C. 112 first paragraph for lack of enablement for the recitation "synergistic in combination" in claim 5, of record stated in the Office Action dated January 8, 2003 has been fully considered and is found persuasive to remove the rejection since this recitation has been removed. Therefore, the said rejection is withdrawn.

Applicant's remarks and amendment which amends claim 6, filed April 8, 2003 in Paper No. 7, with respect to the rejection made under 35 U.S.C. 112 second paragraph

Art Unit: 1617

for indefinite expressions "supercritical" in claims 1-12, and "a...period of time" in claim 6 of record stated in the Office Action dated January 8, 2003 have been fully considered and are found persuasive to remove the rejection. Therefore, the said rejection is withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3 as amended now are rejected under 35 U.S.C. 102(b) as being anticipated by Majeed et al. (5,861,415) for reasons of record stated in the Office Action dated January 8, 2003.

Applicant's remarks filed April 8, 2003 in Paper No. 7 with respect to the rejection of claims 1 and 3 made under 35 U.S.C. 102(b) as being anticipated by Majeed et al. (5,861,415) in the previous Office Action have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art for the following reasons.

extract
~~exact~~ Applicant argues that the instant composition in claim 1 requires a supercritical and a hydroalcoholic extract of turmeric. However, as discussed in the previous Office Action, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The

Art Unit: 1617

patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). The product-by-process claim was rejected because the end product. See MPEP 2113.

Thus, even though product-by-process claims herein are limited by and defined by the process, i.e., the extract of turmeric herein obtained by both supercritical and hydroalcoholic extractions, two processes, the determination of patentability is based on the product itself. Since the end product, the extract of turmeric, is known in the art, the product-by-process claim was rejected because the end product.

Applicant is further requested to note that it is well settled that “intended use” of a composition or product, e.g., effect smoke detoxification in a human, will not further limit claims drawn to a composition or product. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1617

Claim 5, even though it is not anticipated by Majeed et al. (5,861,415, PTO-892) as applicable to claims 1 and 3, is rejected under 35 U.S.C. 103(a) as being unpatentable over Majeed et al. (5,861,415) and "Antioxidant Effects of Tea"(page 249-254) or Applicant's admission regarding the prior art in the specification (see page 5 lines 4-6) for reasons of record stated in the Office Action dated January 8, 2003.

Applicant's remarks filed on April 8, 2003 in Paper No. 7 with respect to this rejection made under 35 U.S.C. 103(a) of record in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

Applicant traverses the rejection and the reasons for the rejection. Nonetheless, as discussed in the previous Office Action, both an extract of turmeric containing curcuminoids and an aqueous extract of green tea are known antioxidants and also known to be useful in a pharmaceutical composition to be administered as antioxidants. Therefore, one of ordinary skill in the art would have reasonably expected that combining an extract of turmeric containing curcuminoids and an aqueous extract of green tea known useful for the same purpose, i.e., being antioxidants, in a composition to be administered would produce additive therapeutic effects in antioxidant activity (not because "all active composition components herein are known to useful to treat and prevent Alzheimer's disease" as stated in the previous Office Action, the examiner conceded). It has been held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for same purpose in order to form a third composition that is to be used for the very same purpose; idea of combining them

Art Unit: 1617

flows logically from their having been individually taught in prior art. *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980. See MPEP 2144.06.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oppenheim et al. (WO 99/20289) and "Antioxidant Effects of Tea"(page 249-254) or Applicant's admission regarding the prior art in the specification (see page 5 lines 4-6) for reasons of record stated in the Office Action dated January 8, 2003.

Applicant's remarks filed on April 8, 2003 in Paper No. 7 with respect to this rejection made under 35 U.S.C. 103(a) of record in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

Again, Applicant argues that the instant composition in claim 1 requires a supercritical ~~extract~~ and a hydroalcoholic extract of turmeric. As discussed above, since
extract

the end product, the extract of turmeric known containing the active ingredient, curcuminoids, is known in the art, the extract of turmeric is not patentable.

Applicant's argument that the composition of Oppenheim et al. (WO 99/20289) may be highly concentrated, chemical solvent free, undamaged by heat..." is not found convincing. Oppenheim et al. clearly discloses that clear herbal extract solutions including turmeric containing curcuminoids, an extract of green tea, an extract of parsley seed, an extract of rosemary, and an extract of ginger (see page 6-9). The processes for extractions in Oppenheim et al. include liquid carbon dioxide, also known as supercritical carbon dioxide extraction, and hydroalcoholic extractions (see page 3 lines 14-21).

As discussed in the previous Office Action, One having ordinary skill in the art at the time the invention was made would have been motivated to optimize the effective amounts of active agents in the composition herein to be administered because the optimization of amounts of active agents to be administered is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

The record contains no clear and convincing evidence of nonobviousness or unexpected results for the combination method herein over the prior art. In this regard, it is noted that the specification provides no side-by-side comparison with the closest prior art in support of nonobviousness for the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,391,364 for reasons of record stated in the Office Action dated January 8, 2003.

Claims 1-4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,264,995 for reasons of record stated in the Office Action dated January 8, 2003.

Applicant's remarks filed on April 8, 2003 in Paper No. 7 with respect to these two rejections of record in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

Art Unit: 1617

First, Applicant asserts that the double patenting rejections are improper based on the legal standard of double patenting since the instant inventors, Thomas Newmark and Paul Schulick, are with New Chapter. However, Thomas Newmark of St. Louis, MO, and Paul Schulick, of Brattleboro, VT, are the same inventors in both patents 6,391,364 and 6,264,995. Therefore, the double patenting rejections are proper based on the legal standard of double patenting.

Secondly, Applicant argues that '995 discloses the composition therein comprising a supercritical carbon dioxide extraction of turmeric or a hydroalcoholic extraction of turmeric. Nevertheless, as discussed in the previous Office Action, although the conflicting claims are not identical, they are not patentably distinct from each other since they are seen to overlap. One of ordinary skill in the art would have found that the instant composition is clearly obvious in view of the patent 6,391,364 or 6,391,364.

In view of the rejections to the pending claims set forth above, no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 1617

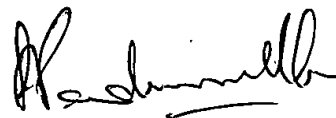
extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
June 4, 2003



SREENI PADMANABHAN
PRIMARY EXAMINER

6/16/03